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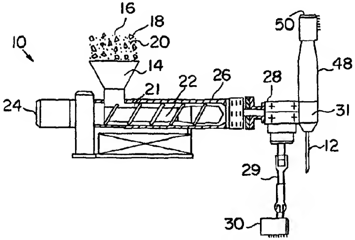

(57) Abstract

A tubing, and a device and method for manufacturing same, involves combining a plurality of strengthening fibers with a polymer matrix. For the method of the present invention, a thermoplastic polymer component is blended with a plurality of liquid crystal polymer particles. This mix is heated to a temperature below approximately 270 °C and extruded to establish the thermoplastic polymer component as a matrix, and to force the particles into elongated fibers embedded in the matrix. Specifically, each fiber is forced into having an aspect ratio greater than about fifty to one. Both the die and mandrel are heated during the extrusion process, to ensure uniform distribution of fibers within the polymer matrix. For the device of the present invention, a passageway is formed between a die and a mandrel through which the polymer mix is extruded. Depending on the particular tubing characteristics desired, the mandrel may or may not be selectively rotated relative to the die during extrusion, resulting in fibers oriented in a helical or a longitudinal configuration, respectively.

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MEDICAL DEVICES MADE BY ROTATING MANDREL EXTRUSION

This application is a continuation-in-part of Application Serial No. 09/020,957, filed February 9, 1998, which is currently pending. The contents of Application Serial No. 09/020,957 are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention pertains generally to polymer shafts and to a device and method for manufacturing same. More particularly, the present invention pertains to medical shafts and tubing which are reinforced with embedded liquid crystal polymer fibers. The present invention is particularly, but not exclusively, useful for the manufacture of such a shaft which incorporates elongated, high aspect ratio reinforcing fibers that may be selectively aligned either longitudinally or helically along the length of the shaft.

BACKGROUND OF THE INVENTION

Catheters and other similar type medical devices which are used interventionally for the treatment of cardiovascular diseases must have certain desirable physical characteristics in order for them to function properly. Included in these characteristics are flexibility, smoothness, biocompatibility, strength, stiffness, kink resistance and resistance to twist. It happens, however, that no one material has an optimal combination of all of these various characteristics. Consequently, it has been necessary to combine different materials in various different ways in order to produce medical devices having acceptably high performance capabilities. In all

cases, of course, it is important that the materials which are used be capable of being processed together. Typically, for interventional medical devices such as catheters and tubing, this process involves extrusion.

It happens that many biocompatible materials which have desirable characteristics for flexibility and smoothness also make inherently weak structures. Consequently, without some form of mechanical reinforcement from other materials, these materials are not generally capable of being maneuvered into and through the cardiovascular system of a patient. Several solutions have been proposed to overcome this problem.

As an example of a multi-material interventional medical device, U.S. Patent No. 5,167,623 which issued to Cianci et al. for an invention entitled "Multilumen Catheter" discloses a device which cooperatively uses different materials having different physical characteristics in different parts of the same product. Yet another example of the combined use of different materials for an interventional medical device is U.S. Patent No. 5,100,381 which issued to Burns for an invention entitled "Angioplasty Catheter." In the Burns device, one material is used as a coating on another material. Additionally, it has been proposed that different materials be mixed together to produce a material having the particularly desired characteristics. One such proposal suggests the use of reinforcing fibers which are embedded into the material. For processes which involve extrusion, however, it is nearly impossible to extrude preexisting reinforcing fibers with the polymer materials that are typically used for the manufacture of catheters and other medical tubing. To overcome this difficulty, some attention has been given to the possibility of using liquid crystal polymer (LCP) fibers in extruded polymer medical devices.

U.S. Patent No. 5,156,785 which issued to Zdrahala for an invention entitled "Extruded Tubing and Catheters Having Increased Rotational Stiffness" suggests using liquid crystal polymers (LCPs) as a reinforcement for tubing and catheters that are used as medical devices. The particular LCPs suggested by Zdrahala, however, are of an earlier known type which require processing temperatures in the range above about six hundred and fifty degrees Fahrenheit or three hundred and forty-five degrees Centigrade. These temperatures unfortunately preclude the use of matrix materials

which otherwise have very desirable characteristics but which are effectively destroyed at temperatures higher than about five hundred and fifty degrees Fahrenheit or two hundred and eighty-five degrees Centigrade.

In light of the above, it is an object of the present invention to provide a device and a method for manufacturing medical tubing and catheters which use incompatible polymers that have processing temperatures below approximately two hundred and seventy degrees Centigrade. Another object of the present invention is to provide a device and a method for manufacturing medical tubing and catheters which use a low-temperature liquid crystal polymer as reinforcing fibers in a matrix to thereby make available a plethora of low-temperature thermoplastic polymers for use as the matrix. Yet another object of the present invention is to provide a device and a method for manufacturing medical tubing and catheters which include solid state low-temperature reinforcing fibers that give the tubing or catheter enhanced strength, stiffness, kink and twist resistant characteristics. Another object of the present invention is to provide a device and a method for manufacturing medical tubing and catheters which orient reinforcing fibers within the tubing, to achieve desired kink and twist resistance characteristics. Yet another object of the invention is to provide a device and a method for manufacturing medical tubing and catheters which have increased strength for both axial translation and torsional rotation. Still another object of the present invention is to provide a device and a method for manufacturing medical tubing and catheters which are respectively easy to use and simple to perform, to produce a resultant product which is comparatively cost effective.

SUMMARY OF THE PREFERRED EMBODIMENTS

A device for manufacturing a shaft in accordance with the present invention includes a polymer extruder which has a heater for melting the polymer, and a drive screw for generating a force on the molten polymer. The device also includes a die, which is formed with a cavity, and which is mounted on the extruder. Additionally, a mandrel is positioned in the cavity of the die. More specifically, the mandrel is distanced from the die to establish a passageway through the cavity between the die

and the mandrel.

The device of the present invention also includes a rotary drive which is connected directly to the mandrel. With this connection, the mandrel can be selectively rotated by the rotary drive of a variable speed motor. Thus, the mandrel is able to provide a turning or twisting action on the molten polymer as it flows through the passageway.

In addition to the above-mentioned heater for melting the polymer in the extruder, both the die and the mandrel of the device also include heating elements. Additionally, resistance thermometry devices, or RTD's, are mounted respectively on the die and on the mandrel. These RTD's monitor the temperature of the molten polymer as it is forced through the passageway, and provide a return signal to a controller. Specifically, the temperature of the molten polymer mix that is in contact with the die is monitored, and the temperature of the molten polymer that is in contact with the mandrel is monitored. According to the monitored temperature, the controller appropriately adjusts the output of the heating elements so that the molten polymer temperature at the die is substantially equal to the molten polymer temperature at the mandrel. In this manner, an effectively even flow profile through the passageway is achieved for the molten polymer at the selected temperature.

The shaft or tube which is manufactured by the device of the present invention is made from a mixture of a plurality of low-temperature thermoplastic polymer particles and a plurality of low-temperature solid state liquid crystal polymer (LCP) particles. More specifically, the polymer and the LCP particles have melting temperatures of less than 270 degrees Centigrade (270° C), with the melting temperature of the polymer being within twenty degrees (20° C) below the higher LCP melting temperature. Further, both the polymer and the LCP particles should be incompatible, in the sense that when heated to their processing temperature, they do not combine with each other. Stated differently, the liquid crystal polymer remains separated from the thermoplastic polymer while the polymer mix is molten.

With specific regard to the LCP particles, during an extrusion process these particles are forced into a plurality of discrete elongated fibers that are embedded in the matrix that is established by the thermoplastic polymer. Preferably, the LCP

fibers will each have an aspect ratio which is greater than approximately fifty to one. Further, the LCP fibers can be oriented to obtain certain shaft reinforcing characteristics. For example, if increased resistance to kinking is primarily what is desired for a shaft, a substantially longitudinal arrangement of LCP fibers is required. On the other hand, if resistance to twist is desired, a helical orientation of fibers is needed. Importantly, by selectively rotating the mandrel relative to the die during the extrusion process, a helical orientation of the LCP fibers in the shaft may be established. Additionally, the pitch of this helical orientation can be altered by changing the speed of rotation of the mandrel to obtain a desired torsional strength for the shaft. Alternatively, with no rotation of the mandrel, the LCP fibers will remain substantially aligned with the longitudinal axis of the shaft.

A method for manufacturing a shaft of the present invention includes the step of blending a low-temperature polymer with a plurality of low-temperature LCP particles. This blending creates a polymer mix which is subsequently heated to a molten state and extruded to manufacture the desired shaft. During extrusion, as a result of extensional flow conditions, the LCP particles are forced from their original particle shape into a fibril configuration. Additionally, the method includes heating the polymer mix, and monitoring the temperatures across the profile of the polymer during the extrusion step to ensure an even flow of molten polymer. Finally, by selectively rotating the mandrel at variable rotational speeds during the extrusion step, the orientation of the LCP fibers can be changed to achieve the desired strength characteristics for the shaft. Specifically, the faster rotational speeds will cause the LCP fibril to assume a higher pitched helical configuration than will be obtained at slower rotational speeds. The result of the method of the present invention is an interventional medical device in the form of a shaft, tubing, or catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of this invention, as well as the invention itself, both as to its structure and its operation, will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

Figure 1 is a side elevational view of an extrusion system used for the practice and manufacture of the present invention with portions broken away for clarity;

Figure 2 is a side elevational cross sectional view of the rotary drive, mandrel and die of the present invention as seen in-plane in Figure 1;

Figure 3 is an enlarged cross sectional view of the mandrel tip and a portion of the die of the present invention as seen in Figure 2;

Figures 4A and 4B are graphical representations of flow velocities of the molten polymer mix through the die of the present invention; and

Figure 5 is a perspective view of a portion of a shaft of the present invention, as manufactured by the device and method of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring initially to Fig. 1, a rotating mandrel extrusion system according to the present invention is shown and generally designated 10. A shaft of the present invention that has been manufactured by the extrusion system 10 is shown and designated 12. As also shown in Fig. 1, a hopper 14 is included within the extrusion system 10 for receiving a polymer mix 16. The polymer mix 16 for use in the present invention is created by blending thermoplastic polymer particles 18 with liquid crystal polymer (LCP) particles 20.

After blending the particles 18, 20, the polymer mix 16 is introduced into the hopper 14 for further processing through the extrusion system 10. As indicated in Fig. 1, the polymer mix 16 is gravity-fed through the hopper 14 into a chamber 21,

which is connected to the hopper 14. Once in the chamber 21, the polymer mix 16 is advanced therethrough by the action of a drive screw 22, which is positioned in the chamber 21 for that purpose. The drive screw 22 is driven by a screw motor 24 which is mounted on the device 10 substantially as shown. The mix 16 advances through the chamber 21 towards a gear pump 28, which is mounted in fluid communication with the chamber 21. The gear pump 28 is turned by a pump drive 29, which is driven by a gear pump motor 30. Both the pump drive 29 and gear pump motor 30 are mounted substantially as shown in Fig. 1.

It is to be appreciated from Fig. 1 that as the mix 16 moves through the chamber 21, the mix 16 is also heated at the same time. For this purpose, a plurality of heating elements 26 are mounted on the device 10 around the chamber 21. These heating elements 26 heat the chamber 21, melting the mix 16 as it advances therethrough. As the polymer mix 16, now in molten form, leaves the chamber 21, it is pressurized by the action of the gear pump 28. This pressure forces the mix 16 through the pump 28 into a die assembly 31, which is directly attached in fluid communication with the gear pump 28.

Referring now to Fig. 2, the advancement of the mix 16 from the gear pump 28 through the die assembly 31 is more clearly shown. After pressurization, the molten polymer mix 16 advances through the outlet 32 of the gear pump 28. The mix 16 is forced from the outlet 32 into a feed passageway 34, which is located in the die assembly 31. This feed passageway 34 is in fluid communication with the outlet 32. After flowing through the feed passageway 34, the mix 16 advances through the extrusion passageway 36, which is in fluid communication with the feed passageway 34. As seen in Fig. 2, this passageway 36 is formed by positioning a mandrel 38 within the cavity 39 of a die 40. Die spacers 42, 44 allow for adjustment of the relative position of the mandrel 38 within the die 40, and are mounted on a die body 46.

It is to be appreciated from Fig. 2 that the mandrel 38 of the present invention is mounted within a mandrel housing 48, which is secured to the die assembly 31. Within this configuration, the mandrel 38 is mounted so that it can be rotated while positioned in the cavity 39 of the die 40. A rotary drive 52 is directly connected to

and drives the mandrel 38. For the present invention, the rotary drive 52 is driven by a variable speed motor 50. Referring back to Fig. 1, the variable speed motor 50 is mounted on the mandrel housing 48, substantially as shown.

Referring now to Fig. 3, the die assembly 31 is shown in more detail. Specifically, the die 40 and adjustable die spacers 42, 44 are secured to the body 46 by a die nut 53. A die bore 54 is included within the die 40, and is in fluid communication with the extrusion passageway 36. Recall that the pump outlet 32 is in fluid communication with the feed passageway 34. In turn, the feed passageway 34 is in fluid communication with the extrusion passageway 36. With this configuration, and as shown in Fig. 3, a flow path for the molten polymer mix 16 is created from the outlet 32 of the gear pump 28 to the die bore 54. In accordance with the present invention, polymer mix 16 exits the die assembly 31 through the bore 54, to form the shaft 12.

It is to be appreciated from Fig. 3 that heating cartridges 56 are included within the mandrel 38, to heat the mandrel 38 during the extrusion process. Additionally, heating elements 58 are mounted on the die 40, to heat the die 40. These cartridges 56 and elements 58 are electrically connected to a temperature controller 60. The controller 60 is also electrically connected to resistance thermometry devices (RTD's) 62, 64, which are embedded within the die 40 and mandrel 38, respectively. These RTD's 62, 64 measure the temperatures at the respective surfaces of the die 40 and mandrel 38, and convert the temperature measurements into electrical signals. The controller 60 receives these electrical signals from the RTD's 62, 64 over lines 66, 68, respectively.

Based on these incoming RTD signals, the controller 60 generates an output, also in the form of electrical signals. These output signals from the controller 60 are routed over lines 70, 72 to the cartridges 56 and elements 58, respectively. The cartridges 56 and elements 58 receive these electrical signals, and convert the electrical signals into a heat output. In this manner, the temperature of the die 40 and mandrel 38 can be controlled during the extrusion process. Only one RTD 62, 64 from the die 40 and from the mandrel 38 respectively is shown, but one skilled in the art would realize that numerous RTD's 62, 64 could be placed in the respective

surfaces of the die 40 and the mandrel 38.

OPERATION

In the operation of the rotating mandrel extrusion system 10 of the present invention, the materials for the thermoplastic polymer particles 18 and LCP particles 20, are first chosen. Preferably, an LCP 20 is used which has a low processing temperature that is in a range between approximately two hundred and twenty, and two hundred and seventy degrees Centigrade (220° C - 270° C). By using such a low temperature LCP 20, it is possible to use a low temperature thermoplastic polymer 18 which also has a low processing temperature. More particularly, in order to avoid destructive effects on the thermoplastic polymer 18 during an extrusion process, it is desirable that the highest extrusion processing temperature of the LCP 20 be not more than about twenty degrees Centigrade above the melt transition temperature of the polymer 18, (T_m). Accordingly, it is desirable that an LCP 20 be used which has a melt transition temperature (T_f) that is less than approximately twenty degrees Centigrade above T_m ($T_f < T_m + 20°$ C).

For the present invention, a thermoplastic polymer 18 having an acceptable processing temperature that is usable with an LCP 20 having a T_f between 220° C - 270° C can be selected from a group consisting of polyamides (nylon), polyurethanes, polyesters and polyolefins. Examples of crystalline melt transition temperatures (T_m) for these materials are respectively:

<u>Polyamides (nylon)</u> - T_m between two hundred and ten and two hundred and seventy-five degrees Centigrade (210 - 275° C);

<u>Polyurethanes</u> - T_m between two hundred and twenty and two hundred and fifty-five degrees Centigrade (220 - 255° C);

<u>Polyesters</u> - T_m between two hundred and twelve and two hundred and sixty-five degrees Centigrade (212 - 265° C); and

<u>Polyolefins</u> - T_m between two hundred and twenty and two hundred and seventy degrees Centigrade (220 - 270° C).

It is also intended for the present invention that the thermoplastic polymer 18

and the LCP 20 be incompatible with each other. Within the context of this invention, the term incompatible is used to mean that the materials, when heated to their processing temperature, do not combine with each other. Stated differently, the LCP 20 remains separated from the thermoplastic polymer 18, even when both are in a molten state in the polymer mix 16.

In addition to the materials, it is also possible to vary the weight ratio of thermoplastic polymer particles 18 to LCP particles 20 to obtain desired properties in an extruded shaft 12. Depending on the desired results, these variations in weight ratio can be made during the processing of a single batch of mix 16, or from batch to batch. Specifically, it has been determined that a variety of materials having slightly different performance characteristics can be manufactured using different ratios. Preferably, for most medical devices, a ratio is established wherein the thermoplastic polymer 18 creates a matrix which is in the range of approximately seventy percent to ninety nine percent by weight and, respectively, the LCP 20 creates fibers which are in the range of approximately thirty percent to one percent (70:30 - 99:1).

Once the materials and desired weight ratios for the thermoplastic polymer particles 18 and LCP particles 20, are chosen, they are blended to form a mix 16, and the mix 16 is introduced to the system 10 through the hopper 14. The drive screw 22 moves the mix 16 through the chamber 21, while at the same time the mix 16 is heated to a molten state by the heating elements 28.

As the polymer mix 16, now in a molten state, leaves the chamber 21, the mix 16 is pressurized by the gear pump 28. After pressurization by the gear pump 28, the molten polymer mix 16 is forced into the die assembly 31 via a feed passageway 34. The molten polymer mix 16 flows through the feed passageway 34 into the extrusion passageway 36, where it comes into contact with the mandrel 38. In this manner, the mandrel 38 can exert a turning or twisting action on the polymer mix 16 as it is forced through the passageway 36. If a tubing instead of a shaft 12 is desired, a hypo tube 55 can be inserted through the mandrel 38 and placed in the die bore 54, as shown in Fig. 3. With this configuration, the polymer mix 16 forms around the hypo tube 55 as the mix 16 exits the die bore 54, forming a tubing.

Like all liquids, the molten polymer mix 16 has internal viscous forces. These

viscous forces in the mix 16 resist flow along the respective surfaces of the mandrel 38 and die 40 during flow through the passageway 36. In general, heating a surface decreases the effect of these viscous forces, resulting in increased flow velocity of a liquid along that surface. More specifically, If the surface of the die 40 is heated during the extrusion process, this heating will reduce the effect of viscous forces along the surface of the die 40. As a consequence, reduced viscous forces will result in greater flow velocities of the mix 16 along the surface of the die 40. If the mandrel 38 is not heated, the effect of greater viscous forces along the surface of the mandrel 38 remain, and flow velocities of the mix 16 along the surface of the unheated mandrel 38 will be slower relative to the surface of the die 40.

As shown in Fig. 4A, velocity arrows 74 represent the velocity of the mix 16 in the passageway 36 when there is differential heating of the mandrel 38 and die 40. More specifically, the situation shown in Fig. 4A is idealized for when only the die 40 is heated. Under these circumstances, the magnitude of the velocity arrows 74 in the molten mix 16 is greater along the surface of the die 40, which is heated. Note that the magnitude of the velocity arrows 74 is much smaller when taken closer to the surface of the mandrel 38, which is unheated. When the velocity arrows 74 are taken across the entire passageway 36, the uneven flow profile 76 results. Such an uneven flow profile 76 for polymer mix 16 can result in a relatively poor distribution of LCP 20 within the extruded shaft 12.

Fig. 4B shows a more even flow profile 78 which is attainable when both the mandrel 38 and the die 40 are simultaneously heated. With an even flow profile 78, it happens that there is a better distribution of LCP 20 within the extruded shaft 12. For this reason, in the device and method of the present invention, the even flow profile 78 is much more desirable than the uneven flow profile 76. As implied above, to obtain the even flow profile 78, the mandrel 38 must also be heated, in addition to the die 40. If the mandrel 38 and die 40 are heated to substantially the same temperature, the viscous forces in the mix 16 will be uniformly reduced along both the surface of the die 40 and the surface of the mandrel 38. With such a uniform reduction, the magnitude of velocity arrows 74 will be generally uniform across the passageway 36, resulting in an even flow profile 76.

For this purpose, the controller 60 monitors the RTD's 62, 64. Based on the readings and measurements of the RTD's 62, 64, the controller 60 adjusts the respective heat outputs of the cartridges 56 and the elements 58. In this manner, the temperatures of the die 40 and mandrel 38 are kept substantially the same during the extrusion process, achieving the desired even profile 76.

Fig. 5 shows an example of an extruded shaft 12 with a lumen 80. From Fig. 5, it is to be appreciated that the LCP particles 20 have elongated into LCP fibers 82 which are embedded within a polymer matrix 84, as a result of the extrusion process. In the preferred embodiment of the invention, the aspect ratio of these fibers 82 is substantially fifty to one (50:1). The orientation of the fibers 82 within the matrix 84 determines the strength properties of the shaft 12, and is also dependent on the selective rotation of the mandrel 38. For example, if the mandrel 38 is stationary during the extrusion process, the manufactured shaft 12 will contain longitudinal LCP fibers 82. With this orientation of longitudinal LCP fibers 82, the shaft 12 will have greatly enhanced resistance to kinking.

On the other hand, by selectively rotating the mandrel 38 during the extrusion process, the mandrel 38 imparts a turning or twisting action on the molten polymer mix 16. As shown in Fig. 5, this turning or twisting action will result in an orientation of helical fibers 86 within the shaft 12. With this arrangement of helical fibers 86, an extruded shaft 12 has enhanced resistance to both twisting and kinking. As another example shown in Fig. 5, an increased rotational speed of the mandrel 38 during the extrusion process will result in the arrangement of modified helical fibers 88. Note that the helical pitch 90 of the fibers 88 is smaller than the pitch 92 of the fibers 86. A shaft 12 with the modified helical fibers 88 will also have resistance to both kinking and twisting. However, a shaft 12 with such an orientation of fibers 88 will have less resistance to kink and more resistance to twist than a shaft 12 with the helical fibers 86. These respective orientations of fibers 82, 86, 88, are achieved through selective rotation of the mandrel 38 during the extrusion process. The result is a reinforced shaft 12 of the present invention.

While the particular shaft or tubing, device or method as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the

advantages herein before stated, it is to be understood that it is merely illustrative of the presently preferred embodiments of the invention and that no limitations are intended to the details of construction or design herein shown other than as described in the appended claims.

What is claimed is:

1. A medical catheter having a shaft, defining a longitudinal axis which comprises:

a low-temperature thermoplastic polymer matrix having a melt temperature (T_m); and

a plurality of low-temperature solid state liquid crystal polymer fibers embedded in said matrix, said liquid crystal polymer fibers having a melt temperature (T_f) with T_f being less than approximately twenty degrees Centigrade above T_m ($T_f < T_m + 20$ °C), and said fibers being substantially arranged in a helical pattern around said longitudinal axis of said shaft and having an aspect ratio (A) greater than approximately fifty to one (A>50:1).

2. A shaft as recited in claim 1 wherein said low-temperature thermoplastic polymer matrix and said low-temperature liquid crystal polymer are incompatible, wherein said thermoplastic polymer matrix is a material selected from the group consisting of polyamides (nylon), polyurethanes, polyesters and polyolefins having processing temperatures below approximately two hundred and seventy degrees Centigrade (270 °C), and wherein said liquid crystal polymer has a processing temperature below approximately two hundred and seventy degrees Centigrade (270 °C).

3. A shaft as recited in claim 1 wherein said thermoplastic polymer matrix and said solid state liquid crystal polymer fibers establish a ratio wherein said thermoplastic polymer matrix is in the range of approximately seventy percent to ninety nine percent by weight and, respectively, said liquid polymer fibers are in the range of approximately thirty percent to one percent by weight (70:18 - 99:1).

4. A shaft as recited in claim 1 wherein said shaft is a tube and said tube is formed with at least one longitudinally extending lumen.

5. A shaft as recited in claim 4 wherein said solid state liquid crystal polymer fibers are arranged in a helical pattern around the center longitudinal axis of said lumen.

6. A shaft as recited in claim 4 wherein said tube is a catheter.

7. A shaft as recited in claim 4 wherein said tube is a balloon in said medical device.

8. A method for manufacturing a medical device having a shaft for use which comprises the steps of:

blending a low-temperature thermoplastic polymer component having a melt temperature (T_m) with a plurality of discrete low-temperature liquid crystal polymer particles having a melt temperature (T_f) to create a mix;

heating said mix to transition both said thermoplastic polymer component and said liquid crystal polymer particles to a substantially liquid phase to create a molten mix;

extruding said molten mix to form said shaft, said thermoplastic polymer component being formed as a matrix and said liquid crystal polymer particles being forced into a plurality of discrete elongated fibers, with each of said fibers being arranged in a helical pattern around the center longitudinal axis of said shaft and having an aspect ratio (A) greater than approximately fifty to one ($A > 50:1$); and

cooling said shaft.

9. A method as recited in claim 8 wherein said low-temperature thermoplastic polymer matrix and said low-temperature liquid crystal polymer fibers are incompatible, wherein said thermoplastic polymer matrix is a material selected from the group consisting of polyamides (nylon), polyurcthancs, polyesters and polyolefins having processing temperatures below approximately two hundred and seventy degrees Centigrade (270 °C), and wherein said liquid crystal polymer fibers have a processing temperature below approximately two hundred and seventy degrees Centigrade (270 °C).

10. A method as recited in claim 8 wherein said blending step is accomplished to create a mix wherein said thermoplastic polymer matrix and said solid state liquid crystal polymer fibers establish a ratio wherein said thermoplastic polymer matrix is in thc range of approximately seventy percent to ninety ninc percent by weight and, respectively, said liquid crystal polymer fibers are in the range of approximately thirty percent to one percent by weight (70:18 - 99:1).

11. A method as recited in claim 8 further comprising the step of forming said shaft as a tube having at least one longitudinally extending lumen.

12. A method as recited in claim 8 wherein said solid state liquid crystal polymer fibers are substantially aligned in a helical arrangement around the center longitudinal axis of said lumen.

13. A method as recited in claim 12 further comprising the step of forming said tube with an integral balloon in fluid communication with said lumen.

14. A method as recited in claim 12 further comprising the step of controlling the speed of extrusion of said lumen, to obtain a desired helical pitch in said helical arrangement.

15. A method as recited in claim 8 wherein T_f is less than approximately twenty degrees Centigrade above T_m, ($T_f < T_m + 20$ °C).

16. A method as recited in claim 15 wherein T is within approximately twenty degrees Centigrade of T.

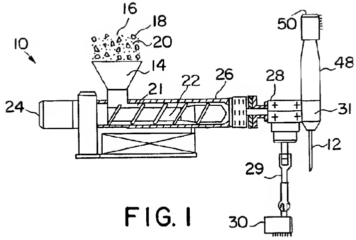
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FIG. 1

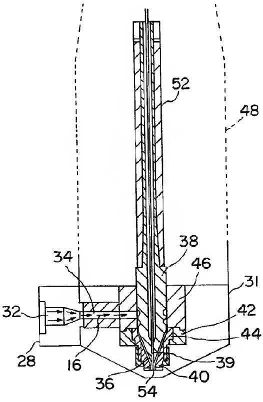
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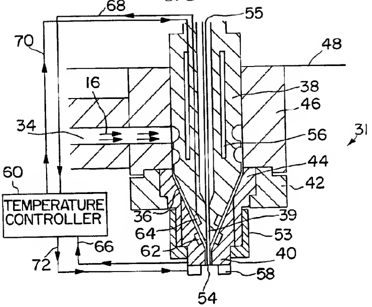
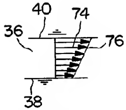
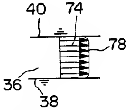
FIG. 2



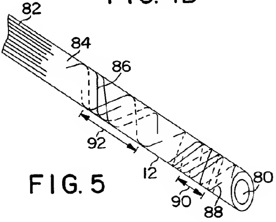
F I G. 3



F I G. 4A



F I G. 4B



F I G. 5

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(74) Agents: LATHAM, Daniel, W. et al.; Medtronic, Inc. MS301, 7000 Central Avenue N.E., Minneapolis, MN 55432 (US).

(81) Designated State (*national*): JP.

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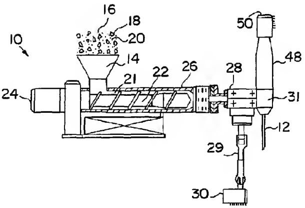
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MEDICAL DEVICES MADE BY ROTATING MANDREL EXTRUSION



(57) Abstract: A tubing, and a device and method for manufacturing same, involves combining a plurality of strengthening fibers with a polymer matrix. For the method of the present invention, a thermoplastic polymer component is blended with a plurality of liquid crystal polymer particles. This mix is heated to a temperature below approximately 270 °C and extruded to establish the thermoplastic polymer component as a matrix, and to force the particles into elongated fibers embedded in the matrix. Specifically, each fiber is forced into having an aspect ratio greater than about fifty to one. Both the die and mandrel are heated during the extrusion process, to ensure uniform distribution of fibers within the polymer matrix. For the device of the present invention, a passageway is formed between a die and a mandrel through which the polymer mix is extruded. Depending on the particular tubing characteristics desired, the mandrel may or may not be selectively rotated relative to the die during extrusion, resulting in fibers oriented in a helical or a longitudinal configuration, respectively.

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61L B29C A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 248 305 A (ZDRAHALA RICHARD J) 28 September 1993 (1993-09-28) column 3, line 44 - line 61 claims	1-16
Y	DATABASE WPI Section Ch, Week 9036 Derwent Publications Ltd., London, GB; Class A96, AN 90-270625 XP002115058 & JP 02 189156 A (MITSUBISHI CABLE IND LTD), 25 July 1990 (1990-07-25) abstract	1-16
A	WO 96 38194 A (SCIMED LIFE SYSTEMS INC) 5 December 1996 (1996-12-05) page 7, line 31 -page 8, line 10 claims	1-14

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 September 1999	11/11/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Thornton, S

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INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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